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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,190	07/31/2001	Hiroki Moriyama	14821	3967

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EXAMINER

JASTRZAB, KRISANNE MARIE

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/919,190

Applicant(s)

MORIYAMA, HIROKI

Examiner

Krisanne Jastrzab

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 8-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Specification***

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Applicant has indicated in the response of 11/15/2004, that the essential material referred to above, is actually present in the original disclosure of the instant application as filed. The Examiner maintains that the specification should then accordingly be corrected to remove the language implying an improper incorporation by reference, for purposes of clarity and completeness. The Examiner would point Applicant to MPEP 608.01 (p) for such authority.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-11 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims as amended, recite a "minimum bend radius", which is not described in the original disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-11 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation in these claims of a "minimum bend radius" is found to be vague and indefinite because it is unclear as to what would actually constitute such a radius.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 8-12 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malchesky '490 in view of Hight, III '751.

Malchesky teaches containment of a lumened instrument with a positioning member for maintaining a predetermined bent configuration of the instrument with structure including a tray and lid, the tray having means therein to maintain the curved configuration of the instrument. Both the lid and tray having means for the ingress and egress of sterilant therein.

Hight, III teaches a pipe portion and a coiled portion for containment of an endoscope during sterilization in order to maintain the curved dimension of the device. Hight, III clearly teaches distal lengths inclusive of a few centimeters up to 200 cm (see column 3, lines 60-65), as well as maintaining the curvature of the receiving vessel to match that of the endoscope (see column 6, lines 20-25).

It would have been obvious to one of ordinary skill in the art to arrange the positioning means of Malchesky such that they address the known and expected curved dimensions of lumened instruments such as endoscopes, those known dimension supported in the disclosure of Hight, III.

Claims 1-3, 8-12 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillebrenner et al., '221 in view of Hight, III '751.

Hillebrenner et al., teach the invention substantially as claimed having a tray with a lid configured with structure to contain an endoscope in a predetermined, curved configuration. The tray and lid are hinged and latched together and having handle means. See column 2, lines 40-48 and 55-68, column 3, lines 1-35, column 6, lines 10-15, 20-25 and 45-60, column 7, lines 64-68, and column 10, lines 58-68.

It would have been obvious to one of ordinary skill in the art to arrange the positioning means of Hillebrenner et al., such that they address the known and expected curved dimensions of instruments such as endoscopes, those known dimension supported in the disclosure of Hight, III.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malchesky and Hight, III as applied to claims 1-3, 8-12 and 14-15 above, and further in view of Morse '758.

Morse teaches that it is known and expected to store lumened instruments in either curved or straight configurations for sterilization (see column 2, lines 20-27).

It would have been obvious to one of ordinary skill in the art to position the means within the device of the combination above such as to accommodate the instrument in a straight configuration where the curve maintenance is not essential, as this configuration is recognized as equivalent.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hillebrenner et al., together with Hight, III as applied to claims 1-3, 8-12 and 14-15 above, and further in view of Morse '758.

It would have been obvious to one of ordinary skill in the art to position the means within the device of the combination above such as to accommodate the instrument in a straight configuration where the curve maintenance is not essential, as this configuration is recognized as equivalent.

***Response to Arguments***

Applicant's arguments filed 6/13/2005 have been fully considered but they are not persuasive. Applicant argues that none of the applied references teach the provision regarding the distal 70 cm as recited in the newly amended independent claims, however, the Examiner would maintain that all cited references clearly teach the desire to maintain a preset curvature to an insertion instrument and that Hight, III clearly teaches lengths of such instruments in a range inclusive of the limitation "at least 70cm" by teaching a few cm up to about 200 cm. Given that all references are concerned with maintaining preset curvatures, it would have been well within the purview of one of ordinary skill in the art to do so within acknowledged lengths of such instruments.

Applicant further argues that the applied references fail to teach stowing an endoscope have an insertion end with a distal observation window, however, the Examiner would maintain that the specifics of the endoscope are not required by the instant apparatus claims, and that the applied structure of the combined references is clearly capable of stowing an endoscope with the cited specifics.

Applicant further argues that the applied references fail to teach restricting the bending of a distal portion of the endoscope, however, the Examiner would disagree and maintain that positioning means that dictate and control the curvature of the article

within the container as set forth in the applied references, clearly function to "restrict the bending" of the article, including the distal portion.

### ***Conclusion***

This is a RCE of applicant's earlier Application No. 09/919,190. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

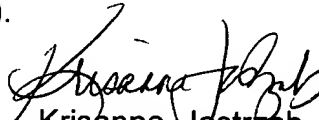
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Wed. 6:30am-4:00pm and alternate Fridays.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Krisanne Jastrab  
Primary Examiner  
Art Unit 1744

August 16, 2005